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09/992,174	11/14/2001	Mario Anthony Moscarello	2132.024	6896

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,174	Applicant(s) MOSCARELLO ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 10 the recitation "associated" is vague. It is unclear what kind of association applicant is referring to.

Claim 1, line 10, "contacting" is vague. How does this contacting differ from other contacting? There are different methods of ELISA testing and thus contacting may be different.

Claim 1, line 16 the recitation "achieved" is not a positive limitation and is vague. It is unclear what it encompasses. Is the diagnosis made or not?

Claim 4, line 2 the recitation "the signal to noise ratio" there is insufficient antecedent basis for this limitation.

Claim 4, line 3 "contacting said sample" is vague. Does this contacting include the compound recited in claim 4, line 1?

Claim 4, line 4 the recitation "high specific affinity" is vague. It is unclear what is considered to be a high specific affinity.

Claim 11, lines 9,11,12, 13, 14, 15 and 18, the recitation "biomolecule" is unduly broad and encompasses more than the specification could possibly support. For

example on page 34 in the specification the only disclosure of the biomolecule used in the kit appears in lines 20 and 21 which exemplifies the use of BMP and anti-MBP-IgG and anti-MBP IgM and no other biomolecules are disclosed in the specification. See also deficiencies found in claims 13-18.

Claim 11, line 16 "one analysis determinative" is vague. How is this analysis performed?

Claim 11, lines 19 and 20 "provides a means for diagnosing or monitoring disease state" is vague. How does this provide a means?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Bloch et al (US Patent 6,183,988).

Bloch et al disclose a diagnostic method for multiple sclerosis which comprises obtaining biological samples form a mammalian body fluid such as sera, plasma, CSF, or saliva. Bloch et al disclose contacting the sample with at least one protein (Sp140) and the contacting is by an enzyme-linked immunosorbent assay (col 22 line 52 – col

23, line 22). Bloch et al disclose detecting the binding of autoantibodies in the serum sample (col 4, lines 1-21). Bloch et al also disclose comparing the level of at least one autoantibody in the first biological sample is measured or estimated and compared to that in a standard taken from an individual not having the autoimmune disease (col 22, lines 37-51). Bloch et al also disclose that at least one protein (Sp140) immobilized on a solid support such as an immunosorbent (col 23, lines 1-8). Bloch et al also disclose the use of a second antibody used for detection. Bloch et al disclose that the identity of this second antibody will depend upon the identity of the mammal for which the biological sample to be tested is derived; for example, if it is a human serum sample, the second antibody will be an anti-human antibody (col 23, lines 17-22).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al (US Patent 6,183,988) in view of Elrod et al (US Patent 5,861,264).

See above for the teachings of Bloch et al.

Bloch et al differ from the instant invention in failing to teach the protein associated with multiple sclerosis as being myelin basic protein.

Elrod et al disclose that multiple sclerosis has been associated with the presence of autoantibodies against myelin basic protein and that multiple sclerosis is

characterized by the presence of autoantibodies against this normal endogenous body constituent.

It would have been obvious to one of ordinary skill in the art to substitute myelin basic protein as taught by Elrod et al for the Sp140 protein of Bloch et al because Elrod et al shows that multiple sclerosis has been associated with the presence of autoantibodies against myelin basic protein and that multiple sclerosis is characterized by the presence of autoantibodies against this normal endogenous body constituent.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al in view of White et al (US Patent 5,821,064).

See above for teachings of Bloch et al.

Bloch et al differ from the instant invention in failing to disclose mixing the sample with at least one compound effective to optimize the signal to noise ratio.

White et al disclose the addition of heparin to an ELISA assay. The addition of this heparin allows for reducing backgrounds, enhancing assay signals and increasing assay sensitivity (col 7, line 60 – col 8, line 8, see also col 4, lines 11-14).

It would have been obvious to one of ordinary skill in the art to incorporate the use of heparin as taught by White et al into the method of Bloch et al because White et al shows that the addition of heparin allows for reducing backgrounds, enhancing assay signals and increasing assay sensitivity.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al (6,183,988) in view of White et al (US Patent 5,821,064) as applied to claims 1, 2, and 4 above, and further in view of Lihme et al (US Patent 6,221,634).

See above for teachings of Bloch et al and White et al.

Bloch et al and White et al differ from the instant invention in failing to teach the signal generating system is a tetramethylbenzidine substrate.

Lihme et al (US Patent 6,221,624) disclose a tetramethylbenzidine substrate. This substrate is especially suitable for enzyme assays such as enzyme-linked-immunosorbent-assays (ELISA), e.g. horseradish peroxide (HRP) is used, and this substrate is storage stable for more than 12 months.

It would have been obvious to one of ordinary skill in the art to incorporate the use of a tetramethylbenzidine substrate as taught by Lihme et al into the method of Bloch et al because Lihme et al shows that this substrate is especially suitable for enzyme assays such as enzyme-linked-immunosorbent-assays, and this substrate is storage stable for more than 12 months.

9. Claims 6, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al (US Patent 6,183,988) in view of White et al (US Patent 5,821,064) as applied to claims 1, 2, and 4 above, and further in view of Voumbourakis et al (Detection of anti-MBP in the serum of patients with multiple sclerosis, Deltion Ellenikes Mikrobiologikes Etaireias, (1992) Abstract Only).

See above for teachings of Bloch et al and White et al.

Bloch et al and White et al differ from the instant invention in failing to teach the autoantibody is anti-MBP IgG and anti-MBP IgM.

Voumbourakis et al disclose determining anti-MBP of the IgG and IgM isotypes. The aim of this study was to investigate anti-MBP in the serum of patients with M.S.

since the occurrence of these antibodies in subjects with multiple sclerosis is controversial.

It would have been obvious to one of ordinary skill in the art determine anti-MBP IgG and IgM as taught by Voumbourakis et al for the method of Bloch et al because Voumbourakis et al teach that the pathogenisis of multiple sclerosis involves antibodies directed against myelin basic protein and that the aim of the study was to investigate anti-MBP in the serum of patients with M.S. since the occurrence of these antibodies in subjects with M.S. is controversial.

10. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al in view of White et al, and Voumbourakis et al as applied to claims 1,2, 4, 6, and 8 above, and further in view of Targoff et al (US 6,160,107).

See above for teachings of Bloch et al., White et al., and Voumbourakis et al.

Bloch et al differ from the instant invention in failing to teach the antibody composition being comprised of anti-human IgG conjugated to horseradish peroxidase and also fails to teach the antibody composition comprised of anti-human IgM conjugated to horseradish peroxidase.

Targoff et al (US Patent 6,160,107) disclose that in order to detect human autoantibodies, a goat anti-human immunoglobulin antibody may be used in a form in which it is conjugated to horse-radish peroxidase. The use of these anti-human antibodies conjugated to horse-radish peroxidase provides methods for detecting autoantibodies found in the sera of individuals (col 4, lines 60-63).

It would have been obvious to one of ordinary skill in the art to incorporate the use of anti-human antibodies conjugated to horse-radish peroxidase as taught by Targoff et al into the method of Bloch et al because Targoff et al shows that the use of these anti-human antibodies conjugated to horse-radish peroxidase provides methods for detecting autoantibodies found in the sera of individuals.

With respect to the anti-human antibodies being IgG or IgM as recited in the instant claims. The IgG and IgM antibodies are response dependent immunoglobulins and it would have been obvious to one of ordinary skill in the art to select the appropriate immunoglobulin for optimization of the method. Also the optimum anti-human antibody as recited in the claims can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

11. Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al, in view of Elrod et al, White et al, Lihme et al, Voumbourakis et al and

Targoff et al as applied to claims 1-10 above, and further in view of Boguslaski et al (US Patent 5,420,016).

See above for teachings of Bloch et al, Elrod et al, White et al, Lihme et al, and Voumbourakis et al.

Bloch et al differ from the instant invention in failing to package the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various reagents into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
March 11, 2002

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03/11/02